

REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks are respectfully requested.

Claims 1, 3-9, 11, 12, 14-22, and 24-51 remain pending in the present application.

In item (1) on page 2 of the April 5, 2007 Office Action, the Examiner states, “[t]his Final Office Action is in response to the “Remarks” and “Amendment” filed on July 10, 2006. This statement raises to two concerns.

First, it is the applicant’s understanding that this Office Action is not a Final Office Action. This understanding is based on two criteria: (1) the Office Action Summary for the April 5, 2007 Office Action (form PTOL-326) indicates that in the Status portion that the action is non-final because box 2b) is checked; (2) the PAIR system indicates the following in the status area “Non-Final Action Mailed”. Thus, there appears to be a discrepancy between the Examiner’s status and the official status of this application.

The second concern has to do with the Examiner’s assertion that April 5, 2007 Office Action is based on or responsive to the July 10, 2006 Amendment. The July 10, 2006 Amendment was not the most recent Amendment filed in this application. Applicant filed an RCE and accompanying Amendment After Final on January 10, 2007. Be that as it may, it does appear that the Examiner considered the January 10, 2007 Amendment in preparing the present Office Action because this Office Action discusses limitations set forth in the January 10, 2007 Amendment, despite the fact that it is not mentioned in item (1) in page 2 of the April 5th Office Action.

The title of the invention has been voluntarily amended to reflect more closely the subject matter of the present invention. Accordingly, applicant respectfully requests that the above amendments to the title be approved.

Claim 1 stands object to because of a minor informality. Claim 1 has been amended above to correct this deficiency. More specifically, claim 1 has been amended to clarify that the pressure generating system functions based on a first operating routine that defines the

operating features for the pressure controller, and that the first operating routine can be modified or upgraded to a second operating routine. Accordingly, applicant respectfully requests that the above objection to claim 1 be withdrawn.

Claims 1, 3-22, 24-31 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 6,305,374 to Zdrojowski et al. ("the '374 patent") in view of U.S. Patent No. 5,715,390 to Hoffman et al. ("the '390 patent") in further view of U.S. Patent No. 5,725,559 to Alt et al. ("the '559 patent"), in further view of U.S. Patent No. 5,881,379 to Beier et al. ("the '379 patent"). In addition, claims 32-51 stand rejected under 35 U.S.C. § 103 as being unpatentable over the '374 patent in view of the '390 patent, the '559 patent, and the '379 patent in further view of U.S. Patent No. 6,094,702 to Williams et al. ("the '702 patent"). Applicant respectfully traverses these rejections for the reasons presented below.

According to the Examiner, the claimed limitation of "[u]pgrading the pressure generating system by causing the controller to execute a second operating routine (sic) so that the pressure generating system operates according to a second set of operating features" is disclosed in the '374 patent. The Examiner gives the following citation on page 4, line 7, of the April 5, 2007 Office Action, "(Zdrojowski: Detailed Description: Paragraph 114)" presumably as the portion of the '374 patent that discloses this limitation. Applicant notes, however, that the detailed description of the '374 patent does not include numbered paragraphs. As a result, it is not possible to determine what portion of the '374 patent the Examiner relies on in support of this conclusion. Applicant respectfully requests that the Examiner identify with specificity the portion of the '374 patent that teaches upgrading the operating system of a controller.

Applicant takes the position that the '374 patent does not teach or suggest causing a controller to execute a second operating routine so that the pressure generating system operates according to a second set of operating features. At best, the '374 patent teaches setting various parameters for the mode of pressure support being delivered to the patient, such as the EPAP, IPAP, breath per minute, and % IPAP settings. However, changing these parameters, which is done manually by the user, does not correspond to upgrading the pressure generating system by

causing the controller to execute a second operating routine so that the pressure generating system operates according to a second set of operating features.

The '374 patent clearly does not teach or suggest the steps of (1) inputting an external access key to the external device, (2) comparing the internal access key provided by the pressure generating system with the external access key, (3) enabling upgrading of the pressure generating system by enabling the first operating routine to be modified responsive to the internal access key matching the external access key, (4) maintaining a database for a plurality of pressure generating systems, wherein the database includes (a) a product identifier unique to each pressure generating system in the plurality of pressure systems, (b) one or more operating routines available to each pressure generating system in the plurality of pressure generating systems, and (c) external access keys associated with each of the one or more operating routines, and (5) updating the database by assigning a new product identifier for an upgraded pressure generating system. For these, the Examiner appears to rely on the '390 patent, the '559 patent, and the '379 patent.

Applicant respectfully submits that the '390 patent is not from an analogous art to the '374 patent, and, thus, should not be applied in combination with the '374 patent to reject the pending claims. Two criteria have evolved for determining whether prior art is analogous: 1) whether the art is from the same field of endeavor, and 2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.... A reference is reasonably pertinent if...it is one which, because of the matter with which it deals, logically would have commended itself to the inventor's attention in considering the problem. *In re Clay*, 23 U.S.P.Q.2d 1058, 1060-61 (Fed. Cir. 1992).

The '380 patent pertains to the field of electrical meters (US class/subclass 395/188). The '374 patent pertains to the field of pressure support therapies for treating breathing disorders (US class/subclass 128/204). On their face, these two references do not come from the same field of endeavor. Also, the '380 patent is not reasonably pertinent to the particular problem with which the inventor is involved because one of ordinary skill in the art in

the medical field would not have logically would have looked to the electrical meter art in considering the problem of how to upgrade the operating routine of a medical device.

According to the Examiner,

“...it would have been obvious for one of ordinary skill in the art to have modified the method of Zdrojkowski with the aforementioned features from Hoffman with the motivation of providing a highly secure method of upgrading a device, as recited in Hoffman, (Col. 36-38). (Note: Even though Hoffman is directed towards an electric meter the concept taught in Hoffman to upgrade an electric meter is similar to the concept of the claimed invention. In addition, the concept of securely upgrading a device or controller in Hoffman can be applied to a variety of devices and machines.)”

See page 3, line 21, through page 4, line 3, of the April 5, 2007 Office Action.

First, it should be emphasized that the ‘374 patent fails to teach or suggest upgrading a pressure support system by enabling a first operating routine to be modified responsive to the internal access key matching the external access key, and causing the controller to execute a second operating routine so that the pressure generating system operates according to a second set of operating features when these keys match. In fact, the ‘374 patent does not teach or suggest modifying the set of operating features at all. The Examiner has not cited any basis for this in the ‘374 patent. Thus, the Examiners reasoning fails at the outset.

Second, the Examiners reasons for combining the ‘374 patent and the ‘380 patent fail, for example, to explain why a highly secure method of upgrading a medical device is even necessary. The Examiner appears to be drawing an inference that this would be desirable, but has not set forth any suggestion existing in the prior art in support of that inference. Also, the mere fact that the concept of securely upgrading a device or controller in Hoffman can be applied to a variety of devices and machines is not sufficient. The fact that elements of the claimed invention exist in the known art does not by itself provide the motivation to make the claimed invention. *See, e.g., In re Newell*, 13, U.S.P.Q.2d 1248 (Fed. Cir. 1989). Furthermore, even the mere fact that the prior art teachings *can* be combined does not support a rejection based on these references. *See, e.g., In re Fitch*, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992).

Applicant submits that it appears that the Examiner is using improper hindsight review of the prior art, using the present invention as an instruction manual or “template” to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This practice has been expressly prohibited by the Federal Circuit. For example, the Federal Circuit has held that “[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention.” *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992)(quoting *In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988)). In the present situation, the Examiner appears to be directed to the references that allegedly teach the claimed limitation by the claims themselves. The Examiner, then recites the teachings from the secondary references, such as providing a secure upgrade as in the case of the ‘380 patent, and being the motivation for the modification.

The Examiner cites the ‘559 patent as teaching the step of “maintaining a database for a plurality of pressure generating systems, wherein the database includes (a) a product identifier unique to each pressure generating system in the plurality of pressure systems, (b) one or more operating routines available to each pressure generating system in the plurality of pressure generating systems, and (c) external access keys associated with each of the one or more operating routines”. Applicant respectfully disagrees.

First, the ‘559 patent does not teach providing a database having (a), (b), and (c). Instead, the ‘559 patent teaches providing a database in the implanted device that contains a plurality of programs and a key associated with each program. See FIG. 4A and col. 9, lines 10-15, of the ‘559 patent. The key to unlock each program is provided by the device manufacturer to enable the implanted device to run the unlocked program, and, hence, be upgraded. This database, because it is stored in the implanted device, does not contain, for example, a product identifier unique to each pressure generating system in the plurality of pressure systems. Nor would it because there would be no reasons for an implanted device to store the product identifier unique to other implanted devices.

The Examiner correctly notes that the ‘559 patent teaches that each implanted device should have its own unique ID. However, the ‘559 patent fails to teach that a database of

these IDs, the operating routines available to each implanted device, and the external access keys associated with each operating routine, should be maintained as a common database outside the implanted device.

Second, the '559 patent pertains to an implanted device. As such, it is very difficult to physically access the device once implanted. In the present invention, the pressure support systems reside outside the body and can be readily accessed for maintenance. Applicant submits that, because of this, one of ordinary skill in the art would not be motivated to look to the relative complicated and complex upgrading procedures taught by the '559 patent in the field of endeavor of the present invention. One of ordinary skill in the art would be likely to use a conventional technique for gaining access to the controller, for example, via a hardwired communication link (RS-232 port, USB port, or the like), and entirely reprogram the processor using conventional reprogramming techniques, which are more efficient than the complicated techniques for the '559 patent.

The Examiner takes the position that the step of "updating the database by assigning a new product identifier for an upgraded pressure generating system" while not disclosed in any of the previous references is taught by the '379 patent. In support, the Examiner cites the "Brief Summary: Paragraph 41" of the '379 patent. This patent, however, does not include numbered paragraphs. As a result, it is not possible to determine what portion of the '379 patent the Examiner relies on in support of this conclusion. Applicant respectfully requests that the Examiner identify with specificity the portion of the '379 patent that teaches this step.

The Examiner goes on to explain that the teachings of the '379 patent would be combined with the prior references "with the motivation of having a means of uniquely identifying each segment of data, including the updated data...." Applicant respectfully submits that the claims recite updating the database by assigning a new product identifier for an upgraded pressure generating system (emphasis added). This step is equivalent to giving an upgraded product a new serial number. This does not correspond to proving a unique identifier for a segment of data. Thus, even if combined, which the Applicant does not admit should be the case, the combination fails to teach or suggest the recited claim limitations.

The above discussion has focused exclusively on independent claim 1. Applicant submits that the distinctions pointed out above with respect to independent claim 1 are equally applicable to independent claims 12, 22, 32, and 49. The additional citation to the '702 patent with respect to claims 32-51 fails to provide the features of the independent claims missing from the '374 patent, the '390 patent, the '559 patent, and the '379 patent.

For the reasons presented above, applicant respectfully submits that independent claims 1, 12, 22, 32, and 49 are not rendered obvious by the cited references. In addition, claims 3-9, 11, 14-21, 24-31, 33-48, 50, and 51 are also not rendered obvious due to their dependency from independent claims 1, 12, 22, 32, or 49. Claims 10 and 13 were cancelled in a previous amendment. Accordingly, applicant respectfully requests that the above rejections of claims 1, 3-22, 24-51 be withdrawn.

All objections and rejections have been addressed. It is respectfully submitted that the present application is in condition for allowance and a Notice to the effect is earnestly solicited.

Respectfully submitted,

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